UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/146,621	10/28/93	FRALEY	R 3821(10640)A

EXAMINER: FOX, D

ART UNIT: 1804 | PAPER NUMBER: 39

18M2/0513

LAWRENCE M. LAVIN, JR.
MONSANTO COMPANY - BB4F
700 CHESTERFIELD PARKWAY NORTH
ST. LOUIS, MO 63198

DATE MAILED: 05/13/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to preliminary communication filed on 10/28/93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 4-11 and 13-28 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 1-2 have been cancelled.
3. ☑ Claims 4-10, 13-15, 19-21 and 26-28 are allowed.
4. ☑ Claims 11, 16-18 and 22-25 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☑ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☑ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

SEE OFFICE ACTION

Applicants' petition to change inventorship is noted. The petition had been approved in parent application Serial No. 07/625,637. Robert B. Horsch has been added as an inventor.

The indication in the last office action in parent application Serial No. 07/625,637 that claims 11 and 16-18 were allowable has been withdrawn in view of the new grounds of rejection below.

Claims 11, 22 and 23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11 and 23 are indefinite in that they are duplicates of each other. The copy of claim 11 that appeared in the Appendix to the Interference papers in parent application Serial No. 07/625,637 was incorrect. Amendment of claim 23 to replace "(35S)" with --(19S)-- would obviate this rejection. Claim 22 is indefinite in its recitation in the preamble of "chimeric gene...plant cells comprising a promoter" as it is unclear which of the preceding claim elements comprises the promoter. Amendment of claim 22, line 1 to insert -- , said chimeric gene -- after "cells" would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains,

or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to provide an enabling disclosure.

The specification only demonstrates the obtention of transformed plants containing a single heterologous gene. It is unclear whether other non-exemplified genes would be successfully expressed, given the lack of appreciable translation of plant genes from divergent species (see, e. g., Larkins et al.). It is also unclear whether the gene product from non-exemplified genes would be expressed at sufficient levels to alter plant phenotype, given the degradation of exogenous nucleic acids and proteins in the plant environment. It is also known that the whole plant possesses many chemical inducers or inhibitors which may be specific for particular differentiated tissues and organs; thus, it is unclear whether genes which might be expressed in individual undifferentiated cells would also be expressed in the whole plant. In addition, the expression of some non-exemplified genes could produce products which would interfere with plant metabolism or divert metabolic intermediates from their native pathways. Finally, the expression of some genes results in phytotoxicity (see, e. g., Barton et al., page 1103, column 2, top paragraph; page 1105, column 2, first full paragraph),

wherein such phytotoxicity could interfere with the viability of individual cells and impair their ability to regenerate into whole plants. Given the unpredictability inherent in the expression of genes in whole plants as discussed supra, undue experimentation would have been required by one of ordinary skill in the art to obtain and evaluate whole plants which have been transformed with a multitude of non-exemplified genes.

In addition, the specification fails to provide an adequate written description of the claimed invention, given the lack of any description of plants containing any non-exemplified foreign gene, the unpredictability regarding the expression of heterologous genes in whole plants as discussed supra, and the uncertainty regarding the effect, if any, of the exogenous gene on the phenotype of the whole plant as discussed supra.

Claims 16-18 and 24-25 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The claims remain free of the prior art, given the unpredictability inherent in the expression of heterologous genes in plants at the time the claimed invention was made, and given the lack of a reasonable expectation of success regarding the expression of heterologous genes in plants under the control of viral promoters, as discussed in the final rejection of parent application Serial No. 07/625,637 mailed 18 December 1991. See also Herrera-Estrella et al. issued May 1983 (D24) which states

that a number of plant, bacterial and animal genes under the control of their own promoters failed to be expressed in transformed plant cells, thus illustrating the unpredictability inherent in the function of heterologous promoters in plant cells.

The art submitted by the Opposition to the European patent has been considered. Most of the art was not pertinent to the instant application, as most of the claims of the European patent were not limited to the 35S and 19S promoters from CaMV. Of the art that pertained to CaMV, none disclosed actual discrete promoters from any CaMV gene, with the exception of Guilley et al. previously considered by the Examiner.

Claims 4-10, 13-15, 19-21 and 25-28 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 12, 1994

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180